REMARKS

The Office Action

Claims 53-85 are pending. Claims 69-71 stand rejected for indefiniteness. Claims 53-63 are allowable over the cited art. Claims 64-85 stand rejected for obviousness over Kahne (U.S. Patent No. 5,780,444).

Support for the Amendments

Support for the amendments to claims 69-71 is based on the inherent units of molecular weight, as discussed in the Reply filed on November 24, 2003 (M.P.E.P. § 2173.05(e)).

Rejections under 35 U.S.C. § 112, second paragraph

Claims 69-71 stand rejected for indefiniteness. The basis for the Office's rejection is that "there is no unit of measurement to accompany the recited numerical values assigned for the molecular weight." Applicants do not believe that any unit is necessary, as one skilled in the art would understand the inherent units of molecular weight. Claims 69-71 have, however, been amended to recite the unit Da, for Daltons, and the rejection may be withdrawn. Applicants further note that support for inclusion of the term "Da" in the claims was previously discussed in the Reply file on November 24, 2003 and accepted by the Office.

Rejections under 35 U.S.C. § 103

Claims 64-85 stand rejected for obviousness over Kahne. Applicants traverse this rejection.

To support an obviousness rejection, the Office must put forth a *prima facie* case that meets the legal standard for obviousness found in M.P.E.P. § 2142. This section states:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure.

Furthermore, "[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done". *Id.* This standard has not been met in the present case.

It appears that the sole basis for the obviousness rejection is that "[i]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose" (M.P.E.P. § 2144.06). The section of the M.P.E.P. relied on by the Office is, however, directed to the physical combination of two prior art compounds and not to the creation of a new chemical compound. This section cites four decisions of the Federal Circuit or CCPA: *In re Kerkhoven* considered the patentability of "a process of preparing

a spray-dried detergent by mixing together two conventional spray-dried detergents..."; *In re Crockett* considered the patentability of "a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide..."; *Ex parte Quadranti* considered the patentability of a "mixture of two known herbicides..."; and *In re Geiger* considered the patentability of a mixture of three components for treating cooling water systems. Thus, M.P.E.P. § 2144.06 contemplates that the *prima facie* obvious mixture of two prior art compounds will contain two separate compounds and not a single compound, as instantly claimed. Claim 64 and its dependent claims are not directed to a mixture of two polyamines having a single hydrophobic group, but to polyamines having two hydrophobic groups. M.P.E.P. § 2144.06 is therefore not relevant to the instant claims, and since this section was the sole motivation to modify Kahne provided by the Office, the Office has necessarily failed in its burden to establish a *prima facie* case of obviousness.

Furthermore, Kahne simply does not teach or suggest all of the limitations of the instant claims. As recognized by the Office, Kahne does not teach the inclusion of two hydrophobic groups. Furthermore, the preferred compounds in Kahne are described as "polyhydroxylated or polyglycosylated steroid molecules, which include amine-containing groups" (col. 1, ll. 25-27).[1] Kahne provides several examples of these compounds and states that "other non-glycosylated amphiphatic steroidal compounds" (col. 18, ll. 42-43) and "other glycosylated amphiphatic steroidal compounds" (col. 19, ll.

[1] *cf* example 6.28 at col. 30

16-17) may be employed (emphasis added). An amphiphatic compound has both hydrophobic and hydrophilic character and does not read on a hydrophobic group. Since Kahne focuses on these amphiphatic compounds that lack a hydrophobic group, it does not suggest a polyalkyleneimine having two hydrophobic groups as recited in the instant claims. Thus, even if there were motivation to link two of the amphiphatic compounds of Kahne together chemically (which there is not), the resulting compound would not teach or suggest the limitations of the instant claims.

The rejection of claims 64-85 for obviousness over Kahne should be withdrawn.

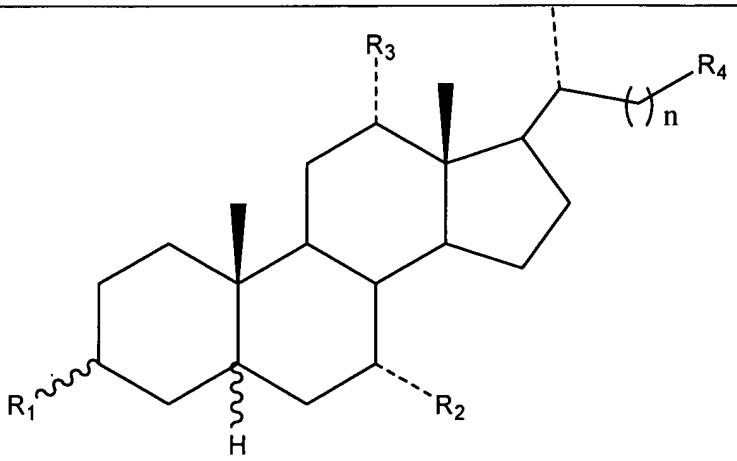
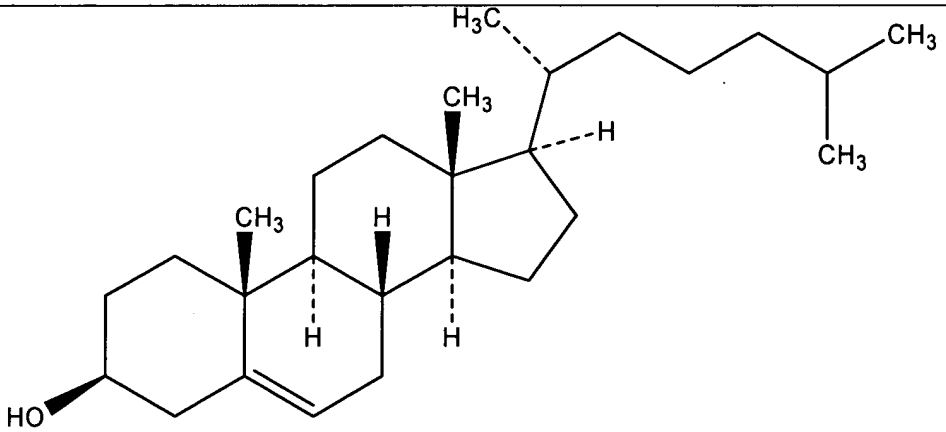
Rejection of Dependent Claims 68, 83, and 85

Dependent claims 68, 83, and 85 recite a list of specific hydrophobic groups that may be incorporated into compositions of the present invention. Claim 68 recites octyl (C_8H_{17}), cetyl ($C_{16}H_{33}$), stearyl ($C_{18}H_{37}$), and oleyl (cis-9 octadecenyl); claim 83 recites $C_{10}H_{21}$, $C_{12}H_{25}$, $C_{14}H_{29}$, $C_{16}H_{33}$, and $C_{18}H_{37}$; and claim 85 recites $C_{16}H_{33}$.

In support of the rejection of these claims, the Office states:

> The method of Kahne comprise contacting a cell with nucleic acid in the presence of a compound of formula I, (see col. 6), this compound has a cholesterol hydrophobic back bone (this portion of Kahne is considered to read on a cholesterol residue, stearyl group, and $C_{16}H_{33}$ hydrophobic groups ...

This statement is scientifically incorrect. The following table compares the structure of Formula I of Kahne with cholesterol, stearyl, and $C_{16}H_{33}$:

Compound	Structure
Formula I	
Cholesterol	
Stearyl	$C_{18}H_{37}$
$C_{16}H_{33}$	$C_{16}H_{33}$

A careful review of Formula I shows that it does not encompass a cholesterol residue because Formula I *requires* a saturated (i.e., no double or triple carbon-carbon bonds) multicyclic structure, while cholesterol is an unsaturated (i.e., it contains a double carbon-carbon bond) multicyclic structure. Furthermore, as

stated above, the preferred compounds of Kahne are polyhydroxylated or polyglycolsyated, but cholesterol contains only one hydroxyl group and is not glycosylated. Stearyl, i.e., an octadecyl radical ($C_{18}H_{37}$), and $C_{16}H_{33}$ are neither cholesterol residues nor encompassed by Formula I. Both stearyl and $C_{16}H_{33}$ are aliphatic groups (i.e., are not cyclic), and both have fewer carbons than either cholesterol (27) or Formula I (minimum of 21). Thus, in contrast to the assertion by the Office, Formula I does not read on either a cholesterol residue, a stearyl group, or a $C_{16}H_{33}$ hydrophobic group. Even if Kahne taught or suggested the limitations of claim 64 (which it does not), it does not suggest the specific groups recited in claims 68, 83, and 85. For this reason as well, the rejection of claims 68, 83, and 85 should be withdrawn.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for reply for two months, to and including August 23, 2005. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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